#### **REMARKS**

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Reconsideration of the subject application is requested in view of the following remarks.

#### I. Claim Status

Claims 23, 24, 27, 29-34, 36, 40-63, and 65 have been canceled, without prejudice or disclaimer. Claims 1-22, 25, 26, 28, 35, 37-39, 64, and 66-85 are pending and at issue.

## II. Anticipation Rejections

## A. Rejections Under 35 U.S.C. § 102(e)

Claims 1-22, 35, 64, and 66-82 remain provisionally rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Application Serial No. 10/719,553 ("the '553 application;" published as U.S. Publication No. 2004/0091500). According to the Examiner, the '553 application "discloses some of the same Bet v 1 mutants, disclosed in the current application." This rejection is traversed on the grounds that the '553 application does not disclose the presently claimed invention.

The '553 application does not anticipate the present claims because it does not disclose every limitation of the claimed invention. MPEP § 2131.01 ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." citing Verdegaal Bros. v. Union Oil Co. of Calif., 814 F.2d 628, 631 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the patent claim." citing Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236 (Fed. Cir. 1989)).

Claim 1 calls for a recombinant allergen, in which at least four primary mutations are spaced from each other by at least 15Å. Each of claims 2-22, 35, 64, and 66-82 include this limitation by virtue of their depending either directly or indirectly on claim 1. The '553 application cannot explicitly disclose the claimed recombinant allergens because it is silent as to the spacing of mutations on recombinant mutant allergens. The '553 application, therefore, cannot explicitly disclose the claim 1 limitation of a recombinant mutant allergen comprising at least four mutations spaced from each other by at least 15Å. Nor does the '553 application inherently disclose an allergen falling within the instant claims. The only example of a recombinant allergen having at least four mutations disclosed in the '553 application is a Bet v 1 mutant with the following four mutations: Asn28Thr, Lys32Gln, Glu45Ser, and Pro108Gly. See '553 application at ¶ 0109; SEQ ID NOS: 36 and 37. The distance between the mutations at the 28 and 32 amino acid positions is only 7.47Å. Thus, at least two of the mutations in the recombinant allergen exemplified in the '553 application are positioned closer to each other than the required distance of "at least 15Å," recited in claim 1. Therefore, the '553 application fails to anticipate the present claims because it does not explicitly or inherently disclose a recombinant allergen having at least four primary mutations spaced at least 15Å from each other.

Finally, the Examiner's citation of claim 26 of the '553 application illustrates that the '553 application does <u>not</u> anticipate the instant claims. Hence, the Examiner fails to point to any allergen mutant set forth in claim 26 having at least four primary mutations spaced at least 15Å from each other. Claim 26 discloses only one allergen mutant with at least four mutations. This is the Bet v 1 quadruple mutant Asn28Thr, Lys32Gln, Glu45Ser, and Pro108Gly. As discussed above, the mutations in this mutant are not all at least 15Å from each other. Hence, the

Examiner cannot point to a mutant in claim 26 wherein there are at least four primary mutations spaced at least 15Å from each other. Claim 26 of the '553 application does <u>not</u> anticipate the instant claims.

For at least the reasons set forth above, the '553 application does not anticipate claims 1-22, 35, 64, and 66-82. The rejection should be withdrawn accordingly.

# B. Rejections Under 35 U.S.C. § 102(b)

Claims 1-22, 35, and 64-82 have been rejected under 35 U.S.C. §102(b) as anticipated by International Publication No. WO 99/47680 ("WO '680"). WO '680 is the international counterpart of the '553 application. The applications have the same disclosure. Accordingly, for the reasons set forth above with reference to the rejection under 35 U.S.C. § 102(e) and the '553 application, WO '680 does not disclose the presently claimed recombinant allergens, in which at least four primary mutations are spaced from each other by at least 15Å.

Nor is it well taken that "One of ordinary skill in the art using the teachings of the '680 patent could readily envisage a mutant allergen with 4 primary mutations, each of which is more than 15 Angstroms apart" (see Final Office Action at page 3, numbered section 4). A chemical genus may anticipate a species "[i]f one of ordinary skill in the art is able to 'at once envisage' the specific compound within the generic chemical formula." MPEP § 2131.02 (citing In re Petering, 301 F.2d 676, 133 USPQ 275 (CCPA 1962)). The primary mutations disclosed in the '680 application and a general disclosure that "the recombinant allergens ma[y] have one or more substitutions" does not allow one of ordinary skill in the art to at once envisage the claimed allergen having 4 primary mutations, each of which is more than 15 Angstroms apart. The '680 application discloses eight primary mutations in Bet v 1. These mutations can be arranged in

8×7×6×5 = 1680 different quadruple mutants. It is telling that of the 1680 possible Bet v 1 quadruple mutants, the Examiner points to only one quadruple mutant that has 4 primary mutations, each of which is more than 15 Angstroms apart. The Examiner derives this mutant, of course, from the instant application. In contrast to the mutants set forth in the instant application, the only quadruple mutant set forth in WO '680 does <u>not</u> meet the spacing requirement called for in the instant claims. Hence, contrary to the Examiner's position, it is <u>not</u> possible to "readily envisage" from the 1680 possible combinations of Bet v 1 quadruple mutants in the '680 application any mutant with at least 4 primary mutations, each of which is more than 15 Angstroms apart.

For at least the reasons set forth above, the present rejection should be withdrawn.

#### III. Obviousness-Type Double-Patenting Rejection

Claims 1-22, 35, 64, and 66-82 have been provisionally rejected under the judicially created doctrine of obviousness-type double-patenting over claims 36-96 of the '553 application. The Examiner alleges that the claims of the instant application are not patentably distinct from the claims of the '553 application ("the '553 claims"). The Applicants traverse this rejection.

"An obviousness-type double patenting rejection must be based on the obviousness standard of 35 U.S.C. 103(a)." MPEP § 1504.06, subsection II. The obviousness standard requires that the invention be considered as a whole (MPEP § 2141.02) and that there be a motivation to combine the references to arrive at the claimed invention (MPEP § 2143.01). The mere presence of elements of the claimed invention in the prior art is not sufficient to arrive at the claimed invention, even if it is possible to physically combine the elements.

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The Examiner contends that the mutants claimed in the instant application are obvious over mutations set forth in claims 36-96 of the '553 application. The '553 claims, however, fail to render the instant claims obvious because they fail to suggest which four (at least), if any, of the mutations in the '553 claims should or could be combined to arrive at the instantly claimed invention. Nor is there any reasonable expectation of success that four mutations in the '553 claims could be combined to arrive at the instant claims. Contrary to a specific suggestion to arrive at the claimed invention that is required to find obviousness, the mere choice of elements from a large number of elements in the prior art to arrive at the presently claimed invention is an "obvious to try standard." MPEP § 2145, subsection X.B; *In re O'Farrell*, 853 F.2d 894, 7 USPQ2d 1673 (Fed. Cir. 1988). "Obvious to try" is not the standard for obviousness. *Id*.

In view of the large number of possible quadruple mutants that could be formed using the mutations set forth in the '553 claims and the absence of any suggestion of to combine any particular set of mutants to arrive at the instantly claimed invention, the must have used the teachings of the instant specification modify the '553 claims and arrive at the instant claims.

Such hindsight is not permitted. *ATD v. Lydall, Inc.*, 159 F.3d 534, 546, 48 USPQ2d 1321, 1329 (Fed. Cir. 1998). ("Determination of obviousness can not be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention. There must be a teaching or suggestion within the prior art, or within the general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources of information, to select particular elements, and to combine them in the way they were combined by the inventor.")

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For at least the reasons set forth above, claims 1-22, 35, 64 and 66-82 are not obvious over claims 39-96 of the '553 application. Reconsideration of claims 1-22, 35, 64, and 66-82 and withdrawal of the obviousness-type double-patenting rejection thereof is requested.

### IV. Conclusion

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining, which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

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